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EXAMINER

ARMSTRONG WESTERN HATTORI
MCLELAND & NAUGHTON
1725 K STREET N W
SUITE 1000
WASHINGTON DC 20006

HINES, J

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/147,052	Applicant(s) Saltoh et al.
Examiner Ja-Na Hines	Group Art Unit 1645

Responsive to communication(s) filed on Jun 27, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 1-17 is/are pending in the application.
Of the above, claim(s) 1, 12, and 13 is/are withdrawn from consideration.
 Claim(s) _____ is/are allowed.
 Claim(s) 2-11 and 14-17 is/are rejected.
 Claim(s) _____ is/are objected to.
 Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Amendment Entry

1. Claims 2, 5, 9-11 have been amended. Examiner also acknowledges amendments to the specification. Claims 1 and 12-13 have been canceled. Claims 2-11 and 14-17 are pending in the office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-11 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 14 now recites a polypeptide causing an antibody-antigen reaction with *M. gallisepticum*. Claim 14 do not reasonably provide proper basis for the use of antibody-antigen reactions. Furthermore, neither the specification nor any of the claims disclose a polypeptide causing an antibody-antigen reaction with *M. gallisepticum*. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

3. Claims 2-11 and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 is indefinite. The specification does not teach how to make additional polypeptides derivatives. The term “derived from” is vague and indefinite, therefore it is unclear what characteristics are needed to determine whether an unknown polypeptide could be considered a derivative polypeptide. The specification neither discloses a definition for a derived polypeptide, nor does it teach a requisite amount of retained qualities needed or characteristics necessary to determine derivative polypeptides.

4. Claims 16-17 are drawn to a vaccine comprising a polypeptide derived from a Herpes outer membrane protein. However neither the claims nor the specification recite a specific protein size, sequence or amino acid fragment, accordingly, there is no teaching that a peptide meeting this criteria will be effective as part of a vaccine.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-10, 14-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200). Sajto et al., (WO 94/23019) teaches novel polypeptides, DNA coding for those polypeptides, recombinant vector containing the DNA, recombinant virus prepared using the vector and various uses (title). “..The polypeptide exhibits the antigenicity of *Mycoplasma gallisepticum*, a fused polypeptide comprising the above polypeptide and connected to the N-terminus thereof, a signal membrane anchor of a type II outer-membrane polypeptide of a virus that infects birds, or a polypeptide capable of reacting with a mycoplasma-immune serum or a mycoplasma-infected serum and exhibiting a substantially pure antigenicity, respectively having amino acid sequences of about 32 kDa, about 40 kDa or about 70 kDa. The expression with a recombinant virus of a polypeptide modified to such as extent as to exhibit an antigenicity equivalent to that of any of the above polypeptides. The use of a recombinant virus as a live vaccine.” (Abstract). The document also teaches that the fused polypeptide can be used as an anti-*Mycoplasma gallisepticum* (MG) infectious disease vaccine and can use the recombinant fowlpox virus (FPV) which has DNA which codes for the signal membrane anchor and can be found by analyzing the hydrophobic peptide region on the N-terminus side of the type II envelop protein in reference to an amino acid sequence. However, Sajto et al., does not specifically recite a polypeptide derived from a Herpes outer membrane protein.

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Yoshida et al., (Virology 1994, vol. 200) teaches the glycoprotein B genes of Marek's Disease Virus Serotypes 2 and 3 and the identification and expression by recombinant fowlpox virus. Marek's disease is a malignant T-cell lymphoma of chickens caused by Marek's disease virus MDV), an avian herpes virus (page 484 para. 1). MDV has been classified as a gamma-herpes virus based upon its tropism, however other studies based upon its gene arrangement indicate that it is more closely related to alpha-herpes virus (page 484 para. 1). The MDV-1 homolog of the herpes simplex virus glycoproteinB (gB) has been cloned and sequenced (page 484 para .3). This gene (gB-1) encodes the B-antigen complex: gp100, gp60 and gp49 (page 484 para. 3). The gB of Herpes Simplex Virus (HSV) is the best characterized of the HSV glycoproteins and it has been shown to be essential for virus infectivity (page 484 para. 5)The gB can be one if the major target of the host immune response and in many herpes viruses, it has been reported that gB homologs are well conserved (page 484 para. 5). The recombinant fowlpox virus (FPV) have been used to express foreign genes and to evaluate their immunogenic potential (page 484 para. 6). Previous studies, show an FPV recombinant expressing the gB-1 gene to elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV (page 484-485-para, 6-1). That data suggest that FPV recombinant is a good candidate for an MDV vaccine and that gB is an important target for the host immune response (page 485 para. 1). An analysis of the predicted amino acid sequences was determined along with a 5' hydrophobic signal sequence which three of the gBps contain (page 487 para. 9). It was

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predicted that the N-terminal hydrophobic region of the gB-1 could serve as a signal sequence (page 488 para .1).

Therefore it would have been obvious to use the polypeptide derived from Yosida et al., (Virology 1994 Vol. 200) with the fusion protein comprising an outer membrane protein that infects birds and vaccine of Sajto et al., (WO 94/23019) because Sajto et al., teaches that the FPV recombinant express the gB-1 gene which can elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV; the FPV recombinant is a good candidate for an MDV vaccine; and that gB is an important target for the host immune response.

6. Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yosida et al., (Virology 1994 Vol. 200) in further view of Yangida et al. Sajto et al., (WO 94/23019) and Yosida et al., (Virology 1994 Vol. 200) have been discussed above, however neither teaches the use of a recombinant avipox virus. Yangida et al., teaches recombinant Avipox virus having all or part of cDNA for Newcastle disease virus derived fused proteins. The recombinant Avipoxvirus has cDNA derived from Newcastle virus inserted into a DNA region non-essential to the proliferation of Avipoxvirus. (page 2 lines 1-3). The method of constructing recombinant vaccinia virus with exogenous DNA into vaccinia virus has been devised and this method is used to obtained live vaccine (page 2 lines 4-6). Accordingly, it is possible to insert a variety of exogenous DNAs depending upon there purpose and the method is expected to used for producing live vaccines (page 2 lines 8-10). The

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inventors have found that recombinant Avipoxvirus genes are effective as vaccine and can prevent infections of Avipoxvirus and Newcastle Disease (page 2 lines 38-43).

Therefore it would have been obvious to use the recombinant Avipox virus with exogenous DNA as taught by Yangida et al., with the fusion polypeptide of Yosida et al., (Virology 1994 Vol. 200) and Sajto et al., (WO 94/23019) because Yangida et al., teaches that recombinant Avipoxvirus genes are effective as vaccine and can prevent infections of Avipoxvirus.

Response to Arguments

7. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants amendments.
8. Claim 13 is objected to under 37 CFR 1.75© as being in improper form because of an improperly dependent claim is withdrawn in view of applicants amendments.
9. Claims 9-12 recites the limitation "a hybrid DNA" in the claims. There is insufficient antecedent basis for this limitation in the claim is withdrawn in view of applicants arguments.

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10. Applicant's arguments filed June 27, 2000 have been fully considered but they are not persuasive. Claims 2-11 and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. Applicants argue that the specification details a description of polypeptides derived from herpesvirus. However claim 14 is indefinite. The specification does not teach how to make additional polypeptides derivatives nor do the claims recite what characteristics are needed to determine whether an unknown polypeptide could be considered a derivative polypeptide. The specification does not disclose a definition or limitations for any derived polypeptide, nor does the specification teach a requisite amount of retained qualities needed or characteristics necessary to determine derivative polypeptides, the specification states only that the starting material is herpesvirus.

11. Claims 9-12 and 16-17 are indefinite is maintained. Claims 9-12 recite DNA coding for the fusion protein, however no specific DNA sequence is recited. It is unclear what the specific amino acids as required in the DNA sequence to code for the fusion protein.

12. Claims 2-10, 14-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200) is maintained. Applicants argue that Sajto et al., does not teach the signal sequence Herpesvirus. In response to applicant's arguments against the references individually, one cannot show

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nonobviousness by attacking references individually where the rejections are based on combinations of references. Sajto et al., in view of Yoshida et al., teaches an analysis of the predicted herpesvirus amino acid sequences was determined along with a 5' hydrophobic signal sequence which three of the gBPs contain and it was predicted that the N-terminal hydrophobic region of the gB-1 could serve as a signal sequence.

Applicants argue that the membrane anchoring sequence of Herpesvirus is not taught and that the antigenicity is not tested *in vivo* but *in vitro* only. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a membrane anchoring sequence of Herpesvirus or whether antigenicity is tested *in vivo or in vitro*) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious to use the polypeptide derived from Yosida et al., (Virology 1994 Vol. 200) with the fusion protein comprising an outer membrane protein that infects birds and vaccine of Sajto et al., (WO 94/23019) because Sajto et al., teaches that the FPV recombinant express the gB-1 gene which

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can elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV; the FPV recombinant is a good candidate for an MDV vaccine; and that gB is an important target for the host immune response.

13. Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yosida et al., (Virology 1994 Vol. 200) in further view of Yangida et al., is maintained. Applicants argue that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, Sajto et al., (WO 94/23019) and Yosida et al., (Virology 1994 Vol. 200) have been discussed above. Yangida et al., teaches recombinant Avipox virus having all or part of cDNA for Newcastle disease virus derived fused proteins. Thus, it would have been obvious at the time of applicants invention to use the recombinant Avipox virus with exogenous DNA as taught by Yangida et al., with the fusion polypeptide of Yosida et al., (Virology 1994 Vol. 200) and Sajto et al., (WO 94/23019) because Yangida et al., teaches that recombinant Avipoxvirus genes are effective as vaccine and can prevent infections of Avipoxvirus.

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14. Applicants submitted a declaration of Shuji Saitoh, Ph.D. This declaration purportedly teaches that inoculation with fNZ7929-67, fNZ7929-66 or fNZ2929XM1 shows better results than with the fusion protein of Sajto et al., (WO 94/23019).

The declaration under 37 CFR 1.132 filed June 27, 2000 is insufficient to overcome the rejection of claims 16-17 because the Declaration does not teach the specific vaccine discussed in the claims. The claims are drawn to a fusion protein as recited in the claims and not the proteins, fNZ7929-67, fNZ7929-66 or fNZ2929XM1, specifically recited in the declaration, therefore the statement that these recited fusion proteins perform better is not commensurate with the scope of the claims.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 

August 28, 2000


JENNIFER GRAETZ
PATENT EXAMINER